

SJ-EXHIBIT 1

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

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1. Program Code	2. Cross File <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Related Files [REDACTED]	3. File No. [REDACTED]	4. G-DEP Identifier
5. By: DI Lewis D. Colosimo At: Pittsburgh, PA D.O.			6. File Title APPROVAL OF APPLICATION (DISTRIBUTOR)	
7. <input type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:			8. Date Prepared 10/26/09	
9. Other Officers:				
10. Report Re: HBC SERVICE COMPANY/GIANT EAGLE, 601 Meadowlands Blvd, Washington, PA 15301 [REDACTED]				

SYNOPSIS

On October 26, 2009, pursuant to the completion of a pre-registration investigation, the Pittsburgh District Office approved an application for DEA registration as a distributor for HBC SERVICE COMPANY. The firm was assigned DEA Registration Number RH0389773.

DETAILS

On July 13, 2009, Gregory CARLSON submitted an application for DEA registration as a distributor in Schedules 3-5 controlled substances for HBC SERVICE COMPANY, a division of GIANT EAGLE, INC., 601 Meadowlands Boulevard, Washington, PA, 15301, Control Number W09164754F. CARLSON is the Director for Pharmacy Sourcing for GIANT EAGLE, INC.

On July 27, 2009, DI Colosimo met with the following personnel from HBC SERVICE CO./GIANT EAGLE: CARLSON, (Director, Pharmacy Sourcing), Andy ZELASKI (Assistant Distributions Operations Manager), Reid Fleming (Director of Loss Prevention and Security), and Dan Beiter (Category Manager). Among the items discussed with regard to the firm's application were proposed recordkeeping and proposed security. Because the firm had not yet installed a security cage for storage of controlled substances, a security test was not completed until a later date.

CARLSON informed DI Colosimo that HBC SERVICE COMPANY will distribute Schedule 3-5 controlled substances to over 200 Giant Eagle pharmacies in Pennsylvania, West Virginia, Maryland, and Ohio. He indicated these

11. Distribution: Division District Other [REDACTED]	12. Signature (Agent) DI Lewis D. Colosimo	13. Date 11-04-09
	14. Approved (Name and Title) Kurt G. Dittmer Group Supervisor	15. Date 11-06-09

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DEFENDANT'S DEPOSITION
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Colosimo

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pharmacies will continue to receive Schedule 2 controlled substances from their current supplier, McKesson Corporation.

After receiving notification from CARLSON that the security cage was installed, on October 26, 2009, DI Colosimo met with CARLSON and ZELASKI to inspect the cage, test the firm's electronic security, and review recordkeeping requirements.

SUBJECT FIRM'S BACKGROUND

HBC (Health and Beauty Care) SERVICE COMPANY, located at 601 Meadowlands Boulevard, Washington, PA, 15301, is a division of GIANT EAGLE, INC., with corporate headquarters at 101 Kappa Drive, Pittsburgh, PA 15238. The subject firm distributes general merchandise, health and beauty aids, and over-the-counter products containing List I chemicals to approximately 210 Giant Eagle supermarkets located in Pennsylvania, West Virginia, Ohio, and Maryland.

HBC SERVICE COMPANY, hereinafter referred to as HBC, was approved as a distributor of List I chemicals on August 27, 1997, and was assigned DEA Registration Number 001753HVY. The subject firm was the subject of in-depth cyclic investigations 2002 [REDACTED], 2004 [REDACTED], and 2008 [REDACTED]. No violations were uncovered during these investigations.

HBC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 3000008128. (See attachment)

RECORDKEEPING

DI Colosimo provided Mr. CARLSON with a current copy of 21 CFR Part 1300 to end. DI Colosimo also provided CARLSON and ZELASKI with a one-page document (see attachment) which listed CFR references for the following topics particularly relevant to drug distributors: ARCOS reporting, Records, Inventory, Storage Cage, storing non-controlled substances with controlled substances, reporting suspicious orders, thefts/losses, confirming the DEA registration numbers for customers, and the proper

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disposal of controlled substances. DI Colosimo reviewed each of these items with CARLSON, ZELASKI, Fleming, and Beiter.

According to CARLSON, because he has been corresponding with Alan Drumheller of DEA HQ regarding ARCOS reporting, he is aware of the reports required for ARCOS.

Regarding the disposal of controlled substances, CARLSON stated HBC expects to use Capital Returns, a reverse distributor, to destroy expired/contaminated controlled substances.

According to CARLSON, HBC will store all original purchase and sales information at their corporate headquarters (Giant Eagle, Inc.) at 101 Kappa Drive, Pittsburgh, PA 15235. DI Colosimo informed CARLSON that because this arrangement is considered central recordkeeping, CARLSON was required to notify the Special Agent in Charge (SAC) of the Philadelphia Division pursuant to 21 CFR 1304.04. CARLSON stated he was aware that records could be kept centrally beginning fourteen days after the SAC received such notification. According to CARLSON, HBC would keep original records at their registered location in the interim period. [Attachment #2 is a copy of correspondence sent to DEA.]

CARLSON stated that HBC may want to store non-controlled substances, including over-the-counter products containing List I chemicals, in the security cage described in the security section of this report. DI Colosimo informed CARLSON that HBC would be required to receive written authorization from the Special Agent in Charge of the Philadelphia Division, pursuant to 21 CFR 1301.72(b)(7)(ii). [Attachment #3 is a copy of correspondence sent to DEA.]

SECURITY

HBC SERVICE COMPANY is the sole occupant of a 305,000 square foot warehouse (constructed of concrete and steel) located within the Meadowlands Industrial Park, a light industrial park in Washington County. A sign at the entrance to the property identifies the tenant as HBC Service Company - nothing that would indicate the presence of List I chemicals or controlled substances. The firm operates five days per week,

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24 hours per day. There are approximately 150 warehouse employees working varied hours.

A visual inspection of the facility revealed passive infrared motion detectors and magnetic contact switches (for all exterior doors, including shipping and receiving doors) were strategically located throughout the firm, appearing to provide adequate security coverage. (See attached warehouse floor plan.) Glass break sensors are located in all rooms with exterior windows. Surveillance cameras are positioned to monitor the employee entrance and receiving door 24 hours per day; video footage is stored for a period of 30 days. The exterior of the warehouse is illuminated from dusk to dawn.

All employees are required to use a radio frequency security card to enter and leave the warehouse. Through this device, the subject firm is able to identify the date and time of employee ingress and egress.

The firm's electronic security is monitored by Sonotrol Security Company. ZELASKI advised the investigators that when an alarm sensor is activated in the firm, a signal is transmitted to Sonotrol, who then notifies the South Strabane Township Police Department, located less than 5 minutes from the firm. After the police department is notified, Sonotrol will call a representative from the subject firm. According to ZELASKI, the firm has not had any break-ins since they were registered by DEA in 1997 to handle List I chemicals. When an alarm is activated, an audible alarm can be heard throughout the warehouse.

ZELASKI stated that in the event of a power outage, the firm's electronic security is maintained through a battery backup.

ZELASKI stated that all warehouse employees are initially hired through Kelly Services, a temporary employment agency. Before an employee is hired, a criminal history background check is conducted. He stated that the firm has a "zero tolerance" policy with respect to employee pilferage, which means that an employee caught stealing merchandise is immediately terminated from employment.

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All controlled substances will be stored in a steel cage measuring approximately 30' width x 40' depth x 22' height. The walls and ceiling of the cage, along with cage doors, are constructed of #10 gauge steel fabric. The door to the cage is equipped with a contact switch. The cage is also equipped with four passive infrared motion detectors. All elements of this cage meet the requirements specified in 21 CFR 1301.72(b)(4).

The security cage is located within a large room (hereinafter referred to as pharmacy room) which is attached to HBC's main warehouse. All interior doors and the one exterior door of the pharmacy room are equipped with contact switches. Passive infrared motion detectors are located throughout the pharmacy room providing adequate coverage. Sixteen security cameras are located within this room. Four security cameras monitor the exterior perimeter of this pharmacy room.

As outlined in the attached "HBC PHARMACY SOP" [Standard Operating Procedures], Zelaski provided DI Colosimo with additional descriptive information regarding the firm's security.

All HBC team members with access to the cage or those involved in handling the controlled substances will undergo the required background checks associated to the following DEA regulations in 21 CFR Part 1300: 1301.76, 1301.90, 1301.92 and 1301.93.

The pharmacy room itself will be limited to HBC team members who have direct day-to-day involvement with any activity necessary to sustain the room. This will be done through key fob (fob) access. Fobs will be required to enter and exit the room. No other team members can enter the room unless granted access by the pharmacy room coordinators or a member of the HBC management team. Access will be granted only for business need: i.e. allowing a team member to haul away and dump a full cardboard bin and only after video confirmation of who is attempting to enter. Union team members with fob access to the room are not permitted to allow anyone to enter this room unaccompanied. Any visitor to the room must be accompanied by a member of the HBC operation's management team. It is possible that team members may have access to the pharmacy room, but will

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be restricted from the cage or any work process associated with handling controlled substances.

The cage inside the pharmacy room that will contain the controlled substances will remain locked at all times when not in use. It is permissible for the cage to be unlocked when in use as long as it is being monitored by the coordinator or a member of the management team. If unlocked, only those in compliance with the previously mentioned DEA regulations are permitted to enter inside. Maintenance personnel will be granted access inside for repair work as long as they are in compliance with the regulations. Keys to unlock the cage will be in possession of the HBC operation's management team only.

Exterior entrance to the pharmacy room will also be controlled through fob access through a man door. Access to the exterior door will only be granted to the management staff and maintenance personnel. When a carrier arrives for either pick up or delivery, a supervisor must be notified. When the supervisor arrives in the room, he/she must view the three exterior cameras before going outside to lock the vehicle in place. HBC has installed a device on the loading dock which essentially seals the garage door entrance and the back door of the delivery truck. (See attached photo.) Therefore, when the delivery truck is backed onto the dock and the device is in place, it is impossible to gain access to the pharmacy room from the building's exterior. Once the vehicle is locked in place, the supervisor will fob back inside. The supervisor will close the exterior door before allowing the driver to enter. The supervisor will ensure the holding area is secure and then scan the fob to allow the driver into the holding area. (See attached photo.) Once the exterior door is closed behind the driver, the supervisor will release the holding area door to fully allow the driver inside the pharmacy room.

The supervisor will then unlock the padlock that secures the grade level garage door. If the delivery contains controlled substances, the supervisor will unlock the cage so the product can be taken directly into the protected area. The reconciliation will take place inside the cage by the receiver, but excluding the driver. If the driver arrives for pick up, the supervisor will follow the same steps indicated for the receiving process before allowing the driver access inside. Once either process is

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complete, the supervisor will again review the video security before going outside to release the truck. If the area is clear, the supervisor will go outside and unlock the secure gates.

RECEIVING

All controlled substances will be delivered to the grade-level garage door that leads directly into the pharmacy room at HBC. Each vendor will be required to ship product against a Giant Eagle generated purchase order.

Each purchase order will show the "ship to" address as 601A Meadowlands Blvd, Washington, PA. Upon arrival, all controlled pharmaceuticals will be immediately taken into the locked controlled cage. The counting of the controlled drugs will take place inside the cage.

HBC personnel will denote any discrepancy directly on the bill of lading as it is signed. This includes overages, shortages and damages.

STORAGE

All controlled pharmaceuticals will be maintained inside the cage at all times from receipt through selection. This encompasses all associated tasks - receiving, storage, replenishment, and selection.

SELECTION

All selection will be performed using Vocollect® directed activity. The Vocollect® system will direct users via headset to the location and quantity of each item to select. As the selector is picking, they will scan the NDC bar code of the item to ensure the exact item is being selected. This will be repeated for all items until all total units are selected. (These tasks are completed one customer at a time.) The controlled substances will be placed inside a #12 white paper bag with a pick list attached to the outside of the bag for ease of customer verification upon delivery. Upon completion of the tasks inside the cage, the tasks will be combined with the generic drug tasks and consolidated

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into the fewest shipping cartons/totes as possible. All totes will be sealed and completed totes will be constructed on pallets by geographical destination. The combining of orders will also take place inside the cage.

INVENTORY CONTROLS

In addition to the self scan audit during selection, HBC will perform random audits of at least 10 percent of the total tasks being completed. After all selection is completed, HBC will cycle count all controlled substances daily as the business is run (currently Sunday through Thursday) and always prior to selecting a new billing cycle. All discrepancies will be researched thoroughly in attempt to find the variance. This will include going through the totes of all completed orders (if they have not shipped yet). It will also include searching all trash receptacles and empty boxes before they are disposed. If discrepancies remain, the HBC Pharmacy Merchandising team will be notified and cycle count adjustments will be made. The Pharmacy Merchandising group will notify all customers to search for any discrepancy with their inbound order.

SHIPPING

All deliveries of pharmacy orders are performed through a dedicated third party courier service - Prestige Delivery Systems. HBC electronically sends a bar coded file for all pharmacy orders to Prestige after all orders are released. The bar code contains carton id and customer name and address, and is used by Prestige and HBC for proof of delivery. Prestige delivers directly to the pharmacy at each location while obtaining customer signature. Each customer verifies seal is intact before signing for the delivery. If the seal is broken, the customer will be required to verify all contents of controlled pharmaceuticals against the accompanying pick list. If the seal is broken and the contents of what is being presented do not match the pick list, the customer must immediately note the exception(s) to Wholesale Customer Service, Pharmacy Customer Service and HBC. The customer must also note if the white bag

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was sealed (stapled). If the white bag is stapled and was not tampered with, an investigation will be launched back at HBC to determine what caused the discrepancy. This investigation will include a review of the self audit bar code scan file, the video security system and the cycle count results following that day's billing run. If the white bag was tampered with, Giant Eagle Loss Prevention will also be notified so they may begin an investigation that may also include the courier service.

As per 21 CFR 1301.74 (e), the firm is responsible for selecting a common or contract carrier which provides adequate security to guard against in-transit losses. The site also addresses the responsibility of the firm, when storing controlled substances in a public warehouse, to select a warehouseman which will provide adequate security to guard against storage losses. As noted below, the firm appears to comply with this site.

The firm will use Prestige Delivery Systems, Inc. to ship all controlled substances. According to the website for Prestige Delivery systems (www.prestigedelivery.com), Prestige provides same day and next day delivery and logistics services to clients throughout the northeast and midwest. The website lists thirty-eight warehouses operated by Prestige. On August 31, 2009, DI Colosimo traveled to one of the Prestige warehouses located in the Pittsburgh Airport Business Park and met with the following representatives from Prestige: T.J. Sgro (Executive Vice President), Ralph Powers (Vice President of Operations), and Mark Pulford (Corporate Sales). Powers informed DI Colosimo that Prestige currently ships controlled substances for three major drug distributors: Amerisource, Cardinal Health, and McKesson.

Mr. Powers informed DI Colosimo that Prestige will ship controlled substances for HBC in the following manner: At a pre-determined time (usually at 1 a.m.) a driver from Prestige will pick up controlled substances from HBC (in sealed totes) and deliver them to one of five Prestige warehouses:

Pittsburgh, PA: 161 Spring Run Road Ext, Bldg 2, Coraopolis, PA 15108
Meadville, PA: 10921 Murray Rd, Meadville, PA 16335
Cleveland, OH: 9535 Midwest Avenue, #104, Cleveland, OH 44125

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Columbus, OH: 4279 Directors Blvd, Groveport, OH 43125

Akron, OH: 4240 Sunnybrooke Rd, Kent, OH 44240

When the orders are delivered to these warehouses, the totes containing the controlled substances are immediately unloaded and placed into a steel cage which is bolted to the floor and whose ceiling is also constructed of steel fencing. When the totes are segregated by their final destination, the totes will then be loaded onto Prestige delivery trucks and delivered either to the pharmacy or to one of the five warehouses for further segregation. According to Mr. Powers, the controlled substances will be stored at each warehouse for only one to three hours. Controlled substances will not be stored at the warehouse overnight or when the warehouse is closed. Powers stated Prestige will maintain the proper chain of custody of controlled substances from pickups at HBC to deliveries to pharmacies.

According to Powers and Sgro, all Prestige warehouses, including their storage cages, are monitored by cameras placed throughout the warehouses. Powers demonstrated to DI Colosimo he was able to remotely view any security cage from his personal laptop. Powers stated it was Prestige policy to weekly audit (random and unannounced) 15 percent of all Prestige drivers. Among other things, this audit consists of ensuring delivery trucks are locked at all times and that drivers are maintaining proper chain of custody of merchandise.

ZELASKI informed DI Colosimo that the following individuals will have access to HBC's storage cage:

Name	Social Security Number	Birthdate
Management		
Kristie Abercrombie-Hilty	[REDACTED]	[REDACTED]
Jeff Biddle	[REDACTED]	[REDACTED]
John Bright	[REDACTED]	[REDACTED]
William Cudlipp	[REDACTED]	[REDACTED]
Walter Durr	[REDACTED]	[REDACTED]
William Hevia	[REDACTED]	[REDACTED]
Leo Plaza-Pointe	[REDACTED]	[REDACTED]
Steven Post	[REDACTED]	[REDACTED]

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Ronald Schad			
Stephanie Summers			
Anthony Tilford Jr.			
John Zelaski			
Support			
Justin Baer			
Brian Becquet			
Daniel Bowman			
William Cooper			
Nathan Danforth			
Julie Dean			
Shawna Flynn			
Christy Hart			
Joyce McConn			
Richard Poland III			
Charles Prigg			
Hourly Warehouse - Union			
Corey Brown			
Irene Byrd			
Nancy Campbell			
Barbara Fink			
Yola Kisling			

NADDIS checks on the above listed names did not reveal negative information. With the exception of John Bright, Ronald Schad, Justin Baer, and Daniel Bowman, NCIC inquiries did not reveal any negative information. Further inquiry, however, indicated that none of these four individuals were charged with any drug-related offenses.

On October 26, 2009, DI Colosimo tested all aspects of the firm's electronic security. The security was operational and deemed adequate. (See Attachment #8, confirmation from Sonotrol Security Systems.)

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ACTION TAKEN

As documented above, all controlled substances will be stored within a security cage within a pharmacy room, located at 601A Meadowlands Boulevard, Washington, PA. At the request of Greg CARLSON, the address on the application submitted by CARLSON will be changed to this address to more accurately reflect the DEA registered location.

With the approval of GS Kurt Dittmer, the application bearing control number W09164754F was approved and was assigned DEA# RH0389773.

ATTACHMENTS

1. Document provided by DEA
2. HBC correspondence regarding central recordkeeping
3. HBC correspondence regarding storing non-controlled drugs
4. Floor Plan
5. HBC SOP
6. Photo of dock seal
7. Photo of holding area
8. Information from Prestige Delivery Systems
9. Security test results
10. Certificate of registration from PA Dept of Health

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